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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/521,104 | 02/14/2005 | Kira Salonijs | VA/H-32622A | 7063 |

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

ABBOTT, YVONNE RENEE

ART UNIT PAPER NUMBER

3644

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/521,104

Applicant(s)

SALONIUS ET AL.

Examiner

Yvonne R. Abbott

Art Unit

3644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-32 is/are pending in the application.
- 4a) Of the above claim(s) 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>1/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group I, claims 22-26 in the reply filed on 9/14/06 is acknowledged. The traversal is on the ground(s) that the methods of Group I are covered by Groups II and III, and it would not be an unnecessary burden for the Examiner to search for prior art for Groups I and IV. This is not found persuasive because with respect to Applicants' first argument the groups are not within the permitted combination of different categories of inventions, namely one apparatus and one process. Further, Applicants even state in their Remarks that the Group IV "is a kit containing two or more vaccines, which within Group I, are combined as one composition"; a kit containing two distinct vaccines is distinctly different from a composition (especially where chemical or biological combinations are concerned).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.

3. Claims 22, and 24-26 are rejected under 35 U.S.C. 102(d) as being barred by applicants' US 6,913,754 Patent which claims priority to Great Britain application

9701897 filed January 1997. Griffiths et al. disclose the use of an immunogenic composition comprising live *Arthrobacter*, and an adjuvant or substance admixed with an immunogen in order to elicit a more marked immune response; wherein it is further disclosed that the *Arthrobacter* can be administered concurrently with other vaccines (which is considered to include an immunogen) with standard routine of farm husbandry. Additionally, Applicants' presently disclose (specification, page 6, para. 3) that the vaccine may be combined with a "conventional" vaccine, and that it is not unduly burdensome and would have been obvious to one skilled in the art to screen a selection of known strains or newly-isolated strains for the identifying characteristics and/or SRS immunogenic properties by screening (specification, page 4, para. 3). It is further disclosed that the *Arthrobacter* has ATCC accession number 55921, and that the composition is in lyophilized form with a sterile diluent.

4. Claims 22 and 25-26 are rejected under 35 U.S.C. 102(d) as being barred by applicants' US Patent 6,627,203 which claims priority to Great Britain application 9701897 filed January 1997. Griffiths et al. disclose the use of an immunogenic composition comprising live *Arthrobacter*, wherein it is further disclosed that the *Arthrobacter* can be administered concurrently with other vaccines (which is considered to include an immunogen) with standard routine of farm husbandry. Additionally, Applicants' presently disclose (specification, page 6, para. 3) that the vaccine may be combined with a "conventional" vaccine, and that it is not unduly burdensome and would have been obvious to one skilled in the art to screen a selection of known strains

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or newly-isolated strains for the identifying characteristics and/or SRS immunogenic properties by screening (specification, page 4, para. 3). It is further disclosed that the *Arthrobacter* has ATCC accession number 55921, and that the composition is in lyophilized form with a sterile diluent.

5. Claims 22, and 24-26 are rejected under 35 U.S.C. 102(d) as being barred by applicants' PCT application (WO 98/33884) published August 6, 1998. Griffiths et al. disclose the use of an immunogenic composition comprising live *Arthrobacter*, and an adjuvant or substance admixed with an immunogen in order to elicit a more marked immune response; wherein it is further disclosed that the *Arthrobacter* can be administered concurrently with other vaccines (which is considered to include an immunogen) with standard routine of farm husbandry. Additionally, Applicants' presently disclose (specification, page 6, para. 3) that the vaccine may be combined with a "conventional" vaccine, and that it is not unduly burdensome and would have been obvious to one skilled in the art to screen a selection of known strains or newly-isolated strains for the identifying characteristics and/or SRS immunogenic properties by screening (specification, page 4, para. 3). It is further disclosed that the *Arthrobacter* has ATCC accession number 55921, and that the composition is in lyophilized form with a sterile diluent.

Claim Rejections - 35 USC § 103

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

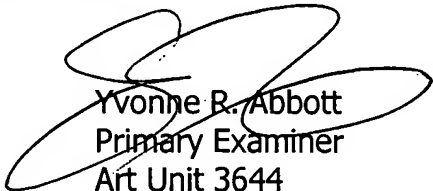
7. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. ('203) in view of Kuzyk et al. (US 2003/0165526). Although Griffiths et al. disclose the use of an immunogen, it is not specifically disclosed that it is selected from the claimed group. Kuzyk et al. teach that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use *Piscirickettsia salmonis* antigen to vaccinate for rickettsial diseases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne R. Abbott whose telephone number is (571) 272-6896. The examiner can normally be reached on Monday-Thursday 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Teri Luu can be reached on (571) 272-7045. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Yvonne R. Abbott
Primary Examiner
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